



CERTIFICATE OF ANALYSIS

Nova 12 Calibrator Pack
Lot Number 508635

Ref Number 15650
Exp Date 2025-12-05
Date of Manufacture 2025-03-05
UDI# (01)00385480156509(11)250305(17)251205(10)508635

Cal A L/N 25073049			Cal B L/N 25073048			Cal C L/N 25064073		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Pass/Fail</u>
Na mmol/L	139.0 - 141.0	Pass	Na mmol/L	69.3 - 70.7	Pass	Na mmol/L	98.0 - 102.0	Pass
K mmol/L	3.97 - 4.03	Pass	K mmol/L	9.8 - 10.2	Pass	Cl mmol/L	87.2 - 90.8	Pass
Cl mmol/L	112.1 - 113.9	Pass	Cl mmol/L	57.4 - 58.6	Pass	NH4	0.88 - 0.92	Pass
HCO3 mmol/L	19.2 - 20.8	Pass	HCO3 mmol/L	9.8 - 10.4	Pass			
BUN mg/dl	9.7 - 10.3	Pass	BUN mg/dl	49.4 - 50.6	Pass			
Glu mg/dl	79.2 - 83.2	Pass	Glu mg/dl	196 - 204	Pass			
Cal J L/N 25066020			Flush L/N 25080006			H L/N 25064059		
	<u>Spec</u>	<u>Pass/Fail</u>		<u>Spec</u>	<u>Result</u>		<u>Spec</u>	<u>Result</u>
Na mmol/L	98.0 - 102.0	Pass	Aqueous Salt	N/A	Present	CO2		
Cl mmol/L	90.7 - 94.4	Pass	Solution			Releasing	N/A	Present
NH4	4.4 - 4.6	Pass				Agent		
Reference L/N 25065041								
	<u>Spec</u>	<u>Pass/Fail</u>						
KCl mol/L	1.8 - 2.2	Pass						

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications. All listed analytes are traceable to NIST SRM Materials.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer.

Approval

QC Inspector
Title

4/4/2025
Date